[reported at 92 F.3d 807]

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

COMMITTEE OF DENTAL AMALGAM MANUFACTURERS AND DISTRIBUTORS; DENTSPLY INTERNATIONAL, INC.

Plaintiffs-Appellees,

v.

JAMES STRATTON, Dr., Interim Director of the Office of Environmental Health Hazard Assessment; DANIEL E. LUNGREN, Attorney General of the State of California,

Defendants-Appellants,

and

ENVIRONMENTAL LAW FOUNDATION,

Intervenor-Appellant.

Nos. 94-56508, 94-56512
D.C. No. CV-93-01439-RMB

OPINION

Appeal from the United States District Court for the Southern District of California

Rudi M. Brewster, District Judge, Presiding

Argued and Submitted March 5, 1996—Pasadena, California

Filed Aug. 5, 1996.

Before: Pregerson, Thomas G. Nelson, Circuit Judges, and Eugene F. Lynch, District Judge.*

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* The Honorable Eugene F. Lynch, United States District Judge for the Northern District of California, sitting by designation.

COUNSEL

Susan S. Fiering, Deputy Attorney General, Oakland, California, for the defendants-appellants.

James Wheaton, Environmental Law Foundation, Oakland, California, for the intervenor-appellant.

Stanley W. Landfair, McKenna & Cuneo, San Diego, California, for the plaintiffs-appellees.

OPINION

PREGERSON, Circuit Judge:

The defendants, Dr. James Stratton, Acting Director of the California Office of Health Hazard Assessment, and Dan Lungren, the Attorney General of the State of California (collectively the "State"), and the intervening party, Environmental Law Foundation ("ELF"), appeal the district court's grant of summary judgment in favor of the plaintiffs, Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply International, Inc. (collectively the "manufacturers"). The district court held that, as applied to dental amalgam, the Medical Device Amendments to the federal Food, Drug and Cosmetics Act ("MDA"), 21 U.S.C. § 321-394, preempt California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), Cal. Health and Safety Code §§ 25249.5-25249.13. The district court had jurisdiction under 28 U.S.C. § 1331. This court has jurisdiction under 28 U.S.C. § 1291. We reverse.

BACKGROUND

Proposition 65 was passed by the voters of California in 1986. Proposition 65 mandates that the public be informed about products that pose a health risk. Proposition 65 specifically states:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.

Cal. Health & Safety Code § 25249.6.

Similarly, Congress enacted the MDA "to assure the reasonable safety and effectiveness of medical devices intended for human use." *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1455 (9th Cir. 1995) (citing H. Conf. Rep. No. 1090, 94th Cong., 2d Sess. *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1103). Manufacturers of medical devices are required to register each medical device with the federal Food and Drug Administration ("FDA") prior to commencing manufacture. 21 U.S.C. § 360(c). Failure to register a device is punishable by fines, penalties, and/or imprisonment. 21 U.S.C. § 333.

The MDA grants the FDA broad authority to regulate medical devices. 21 U.S.C. § 371(a). Under the MDA, the FDA must classify medical devices into three categories, according to the level of regulatory control the FDA determines is necessary to ensure the safety and effectiveness of each device. *See* 21 U.S.C. § 360c. Medical devices which pose little or no threat to public health are classified as Class 1 devices and are subject to only "general controls" related to their manufacture. *See* 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). Medical devices which involve some risk of injury are classified as Class II devices and are subject to "special controls," including performance standards, use guidelines, and post-market surveillance programs. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). Medical devices that pose a high risk of injury or that are implanted in the body are classified as Class III devices and must receive premarket approval from the FDA. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e; 21 C.F.R. §§ 814.1(c), 860.3(c)(3).

Dental amalgam is used by dentists to restore teeth. On July 1, 1990, pursuant to Proposition 65, the State of California listed mercury as a chemical known to cause reproductive harm. 22 Cal. Code of Regulations § 12000(c). As a result, consumer warnings for dental amalgam are now required. This requirement is satisfied through "general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Cal. Health & Safety Code § 25249.11(f).

On September 21, 1993, the manufacturers filed this action seeking a judgment declaring Proposition 65 preempted by the MDA as it applied to dental amalgam. On November 5, 1993, the State filed a motion to dismiss or, in the alternative, for summary judgment. The manufacturers responded by also filing a motion for summary judgment. On August 25, 1994, the district court denied the State's motion and granted the manufacturers' motion for summary judgment on preemption grounds. The district court entered judgment in the manufacturers' favor on September 27, 1994.

Both the State and ELF timely filed separate notices of appeal. On October 11, 1994, the State initiated its appeal. ELF initiated its appeal on October 18, 1994. Both appeals were consolidated on January 6, 1995.

DISCUSSION

I. STANDARD OF REVIEW

We review de novo "the district court's grant of summary judgment on a pure question of law, in which there are no disputed facts." *Kennedy*, 67 F.3d at 1455 (citing *Turner v. Prod*, 707 F.2d 1109, 1114 (9th Cir. 1983)). Further, where, as here, the validity of a statute is being challenged, there must be a showing "that no set of circumstances exists under which the . . . [statute] would be valid." *Chemical Specialties*

Mfrs. Ass'n, Inc. v. Allenby ("*Allenby*"), 958 F.2d 941, 943 (9th Cir. 1992) (" 'the fact that the . . . Act might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid' ") (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). Thus, to find that Proposition 65 is preempted by the MDA, we "must determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions of the" MDA. *Id.* (emphasis added).

II. WHETHER DENTAL MERCURY IS A "MEDICAL DEVICE" UNDER THE MDA

The district court assumed that dental amalgam is regulated by the MDA as a "medical device" because its two component parts—dental mercury and amalgam alloy—are classified by the MDA. As the district court explained:

> The court need not consider whether the FDA is treating dental amalgam as a device, whether it believes it is regulating dental amalgam, or whether it intends to regulate dental amalgam. The court finds, as a matter of logic, that any regulation of dental mercury will, ipso facto, regulate any product containing dental mercury, including dental amalgam. Therefore, this court's ruling extends to dental amalgam. The court need not reach amalgam alloy as Proposition 65 does not regulate it.

Thus, as a threshold matter, we must decide whether the district court was correct in holding that the MDA applied to dental amalgam. Congress defined the term "medical device" very broadly as:

> [a]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, parts or accessory, which is—

> (1) recognized in the official National Formulary, or the United States Phamacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (emphasis added).

Based on this broad definition of "medical device," we hold that dental amalgam does fall within the reach of the MDA. Dental amalgam is used in the treatment and prevention of tooth decay. Further, the FDA has already classified the component parts of dental amalgam. Dental mercury is classified as a Class 1 device. 21 C.F.R. § 872.3700. Amalgam alloy is classified as a Class II device. 21 C.F.R. § 872.3050. Thus, there can be no question that any regulation of dental mercury or amalgam alloy under the MDA also applies to dental amalgam.

III. GENERAL PREEMPTION PRINCIPLES

There is a strong presumption against finding that state law is preempted by federal law. *Allenby*, 958 F.2d at 943. As the Supreme Court recently stated:

> [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the as-

> sumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."

Medtronic, Inc. v. Lohr, ___ U.S. ____, 116 S. Ct. 2240, 2249 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Thus, "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Id.* at 2245 (citations and quotations omitted).

In addition, a court's analysis as to the scope of preemption is guided by Congress's purpose in enacting the statute at issue. *Id.* at 2250. Congress's purpose "is discerned from the language of the pre-emption statute and the 'statutory framework' surrounding it" as well as from "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers and the law." *Id.* (citations omitted).

IV. PREEMPTION UNDER THE MDA

Congress included an explicit preemption provision in the MDA. Section 360k(a) provides:

> [N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) *which is different from, or in addition to,* any requirement applicable under this chapter to the device, and
>
> (2) *which relates to the safety or effectiveness of the device* or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

In *Medtronic v. Lohr*, the Supreme Court rejected a broad construction of this preemption provision. In *Medtronic*, the

manufacturer of a Class III device was sued under state law for damages caused by a defective pacemaker. The manufacturer argued that plaintiff's state causes of action were preempted by the MDA because they qualified as state "requirement[s] . . . different from . . . [and] in addition to" the federal standards and "requirements" promulgated by the FDA. *Id.* at 2250.

The Supreme Court found the manufacturer's arguments "not only unpersuasive . . . [but also] implausible." *Id.* As the Supreme Court explained:

> Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices. . . . Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation . . . . It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," . . . and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

Id.

Based on this reasoning, we hold that our prior decisions narrowly construing the MDA's preemption clause are consistent with *Medtronic v. Lohr*. Before Medtronic, we already had rejected a broad construction of the MDA preemption clause. *See Kennedy v. Collagen*, 67 F.3d 1453, 1457 (9th

Cir. 1995); *Anguiano v. E.I. DuPont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995). As we explained in *Kennedy*:

> [T]he statutory language of § 360k(a) does not create the broad, sweeping preemption found by . . . [other circuits]. Reading 360k(a)(1) broadly requires recognizing that *any* state law is, by definition, a law "in addition to" federal law. A broad reading of § 360k(a) thus renders the "different from" language meaningless and forces a strained reading of the statute.

Id.

Further, in determining what kind of federal "requirement" and what kind of state "requirement" trigger preemption, the Supreme Court in *Medtronic* deferred to the FDA's regulation that narrowly construes the MDA's preemption clause. 116 S. Ct. at 2260-63. Section 808.1(d) provides, in relevant part:

> State or local requirements are preempted *only* when the Food and Drug Administration has established *specific counterpart* regulations or there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition, the *specific* Food and Drug Administration requirement . . . .

21 C.F.R. § 808.1(d) (emphasis added).

Based on this FDA regulation, a state or local "requirement" is preempted by the MDA only if specific counterpart requirements or regulations that are applicable to a *particular* device exist. As the Supreme Court explained:

> [P]reemption under the MDA does not arise directly as a result of the enactment of a [state] statute; rather, in most cases a state law will be preempted only to the extent that

> the FDA has promulgated a relevant federal "requirement."

116 S. Ct. at 2255. *See also Anguiano v. E.I. DuPont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995) ("the scope of preemption is limited to instances where there are *specific* FDA requirements applicable to a *particular* device") (emphasis added).[1]

In addition, the Supreme Court in *Medtronic* specifically approved that part of the FDA regulation that provides that "[s]ection 521(a) does not preempt State and local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d). As the Supreme Court explained, the word "[r]equirement appears to presume that the State is imposing a *specific* duty upon the manufacturer." 116 S. C. at 2251 (emphasis added). Thus, a state law of general applicability will be preempted only if it has "the effect of establishing a substantive requirement for a specific device." *Id.* at 2262.

V. WHETHER PROPOSITION 65 IS PREEMPTED BY THE MDA

The district court held that, even though the FDA has not established "specific" regulations relating to dental amalgam, the MDA still preempts Proposition 65. First, the district court held that 21 C.F.R. § 801.109, the FDA regulation describing the manufacturing and labeling requirements, is

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[1] In 1990 and 1992, Congress amended the MDA while leaving 21 C.F.R. § 808.1(d) intact. If Congress disagreed with the FDA's interpretation of the MDA's preemption clause, Congress would have amended the MDA at that time. Because Congress did not do so, it is fair to assume that the FDA's interpretation of the MDA's preemption clause is consistent with Congressional intent.

"specific" enough to trigger preemption. Second, the district court held that the FDA's alleged refusal to impose reproductive toxicity requirements on dental mercury is by itself preemptive.

The district court was wrong on both counts. In *Medtronic*, the Supreme Court held that the FDA's manufacturing and labeling requirements were *not* "specific" enough to preempt state law. 116 S. Ct. at 2263. As the Supreme Court explained:

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

116 S. Ct. at 2257.

Further, Proposition 65 is a state law of general applicability which was *not* enacted "with respect to" medical devices. Proposition 65 applies to *all* products and services that pose a health risk to the public. Except for identifying chemicals known to pose a health risk, Proposition 65 is not directed at any product or industry. Nor has the State of California adopted any *specific* regulation or requirement that relates to dental amalgam. The State of California has listed mercury as a product which causes reproductive harm. As a result, consumer warnings for dental amalgam are now required.

Thus, we hold that the consumer warning requirement under California's Proposition 65 is not "specific" enough to trigger preemption because it is "not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." 116 S. Ct. at 2257. As the Supreme Court explained in *Medtronic*:

> General obligations are not more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in training and supervision of a workforce. These state requirements therefore escape preemption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices.

Id.

We also reject the district court's holding that the FDA's *failure* to impose a warning requirement on dental amalgam is by itself preemptive. Inherent in the term "requirement" is the idea that there be a positive enactment from the FDA before preemption can be triggered. As the Supreme Court explained in *Medtronic*:

> [T]he word ["requirement"] is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies. . . . For instance, subsections (a)(2) and (b) of the statute also refer to "requirements"—but those "requirements" refer only to statutory and regulatory law that exists pursuant to the MDA itself, suggesting that the pre-empted "requirements" established or continued by States also refer primarily to positive enactments of state law.

116 S. Ct. at 2252.

To hold that inaction by the FDA is sufficient to trigger preemption would mean that manufacturers would be free to ignore state laws that are intended to protect consumers, during the period that the FDA is considering whether to issue specific regulations relating to particular products, or after the FDA, for whatever reason, has "decided," through inaction, not to regulate particular products. Such a holding would contradict Congress's stated intent of providing consumer protection from unsafe medical devices when it enacted the MDA. *See* 43 Fed. Reg. 18,663 (May 2, 1978).

CONCLUSION

As set forth above, the district court's grant of summary judgment in favor of plaintiffs is reversed. We conclude that California's Proposition 65 is not preempted by the MDA.

REVERSED AND REMANDED.

[unreported]

FILED
SEP 16 1994
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY /s/ DEPUTY

United States District Court
Southern District of California

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS, et al., Plaintiffs,

vs.

DR. CAROL HENRY, et al., Defendants.

ENVIRONMENTAL LAW FOUNDATION, Intervenor.

Civil No. 93-1439-B(BTM)

ORDER AMENDING PREVIOUS ORDER OF 8/24/94 TO DENY PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE AS MOOT

The court hereby orders that this court's order filed on August 24, 1994, and bearing the caption "ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF PREEMPTION; DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE VIOLATION; DENYING DEFENDANTS' AND INTERVENOR'S MOTIONS TO DISMISS OR FOR SUMMARY JUDGMENT; AND DENYING DEFENDANTS' MOTIONS TO STRIKE AND FOR DISCOVERY," be amended by this order.

Sections IV and V(2) of the August 24, 1994 order are amended to reflect that the plaintiffs' motion for summary judgment on its declaratory relief claim based on a violation of the Commerce Clause is denied as moot.

IT IS SO ORDERED.

DATED: SEP 15 1994

/s/

UNITED STATES DISTRICT JUDGE

cc: All Parties

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[reported at 871 F. Supp. 1278]

FILED
AUG 24 1994
CLERK, U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA
BY DEPUTY

United States District Court
Southern District of California

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS, et al., Plaintiffs,

vs.

DR. CAROL HENRY, et al., Defendants.

ENVIRONMENTAL LAW FOUNDATION, Intervenor.

Civil No. 93-1439-B(BTM)

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON ISSUE OF PREEMPTION;

DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT ON ISSUE OF COMMERCE CLAUSE VIOLATION;

DENYING DEFENDANTS' AND INTERVENOR'S MOTIONS TO DISMISS OR FOR SUMMARY JUDGMENT; AND

DENYING DEFENDANTS' MOTIONS TO STRIKE AND FOR DISCOVERY

Plaintiffs' motion for summary judgment, defendants' and intervenor's motions to dismiss, or in the alternative for summary judgment, and defendants' motions to strike the declaration of David Link and for additional discovery, were heard before the Honorable Rudi M. Brewster on May 16, 1994. Stanley Landfair, Esq., and Carol Brophy, Esq., appeared for plaintiffs; Susan Fiering, Esq., appeared for the

State defendants; James Wheaton, Esq., and Alice Chang Kaufman, Esq., appeared for the intervenor defendant. The court continued these motions for supplemental briefing and further review. Upon further consideration of the moving and responding papers, the supplemental briefs and submissions,[1] the court hereby GRANTS summary judgment for plaintiffs on the issue of preemption, DENIES plaintiff's motion for summary judgment on the Commerce Clause claim, and DENIES defendants' motions.

I. Background

Plaintiffs brought this declaratory and injunctive relief action seeking a determination that a California state statute, the California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), Cal. Health & Safety Code §§ 25249.5-25249.13, is preempted by the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 321-394, in so far as Proposition 65 imposes warning requirements for dental mercury that are different from or in addition to requirements under the MDA. Plaintiffs also contend that Proposition 65 violates the Commerce Clause.

Proposition 65 states:

> **§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity**
>
> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical

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[1] The court requested supplemental briefs, of no more than ten pages, on the issue of labelling. The court declines to consider plaintiffs' June 7, 1994, letter because it exceeds the court's request. The court accepts ELF's May 12, 1994, letter and plaintiff's May 23, 1994, letter, because they cite recently-decided authority. The court accepts all three supplemental briefs.

> known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.
>
> **§ 25249.10. Exemptions from warning requirement**
>
> Section 25249.6 shall not apply to any of the following: (a) An exposure for which federal law governs warning in a manner that preempts state authority . . . [or] (c) An exposure for which the person responsible can show that the exposure poses no significant risk . . . .

The State of California has listed dental mercury as a "chemical known to the state to cause . . . reproductive toxicity."

All medical devices are classified under the MDA. Dental mercury is a Class I device regulated by the MDA. *See* 21 C.F.R. § 872.3700(b). The federal Food and Drug Administration ("FDA") has defined dental mercury as "a device composed of mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or a broken tooth." *Id.* Amalgam alloy is a Class II device. *See* 21 C.F.R. § 872.3050. Dental amalgam, which is the combination of dental mercury and amalgam alloy, is not a "device" under the MDA. However, to the extent that its two component parts are regulated by the MDA, dental amalgam is, ipso facto, regulated by the MDA.[2]

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[2] The court need not consider whether the FDA is treating dental amalgam as a device, whether it believes it is regulating dental amalgam, or whether it intends to regulate dental amalgam. The court finds, as a matter of logic, that any regulation of dental mercury will, ipso facto, regulate any product containing dental mercury, including dental amalgam. Therefore, this court's ruling extends to dental amalgam. The court need not reach amalgam alloy as Proposition 65 does not regulate it.

All medical devices, whether Class I, II, or III, are subject to "general controls." *See* 21 U.S.C. § 360c(a)(1)(A). The general controls include a provision for labeling and warnings. *See* 21 U.S.C. § 352(f). Section 352(f) states:

> A drug or device shall be deemed to be misbranded—
>
> . . . Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

The Secretary has promulgated regulations exempting prescription devices from the requirement of clause (1). *See* 21 C.F.R. § 801.109.[3] Section 801.109 states, in relevant part:

> A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section

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[3] From oral argument, the court understands that dental mercury and amalgam alloy traditionally were mixed in the dentist's office, but more recently are sold pre-packaged in capsule form. The court requested plaintiffs to submit a sample of labelling for dental amalgam capsules to enable it to understand the application of this regulation to dental mercury, not to determine whether plaintiffs' labelling complies with the regulation, which is not at issue in this case.

502(f)(1) [352(f)(1)] of the act if all of the following conditions are met:

(a) The device is:

(1) (i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) . . .

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however*, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) . . .

(e) . . . .

In addition, the statute provides that the FDA has the authority to impose any necessary warning requirements on medical devices. *See* 21 U.S.C. § 360h(a). The relevant part of § 360h(a) states:

> If the Secretary determines that—
>
> (1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and
>
> (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,
>
> the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. . . .

There is no genuine issue of material fact that the FDA has considered, and rejected, imposing reproductive toxicity warning requirements for dental amalgam. *See* Brophy Decl., Exhs. 5, 7, 14, 17, 28-31, 33; Link Decl. at 60- 61;[4] 40 Fed.

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[4] Defendants have moved to strike the Declaration of David Link, who managed the FDA's medical device program from 1970 to 1980. This motion is DENIED. Defendants also have requested that the court grant them leave to conduct additional discovery on the FDA's consideration of, and rejection of, warnings for reproductive toxicity. This request also is DENIED. Defendants had ample opportunity to conduct discovery, as this motion was continued several times at the parties' request. Furthermore, FDA's consideration of imposing reproductive toxicity (Footnote continued on next page)

Reg. 21,848 (May 19, 1975); 42 Fed. Reg. 60,193 (Nov. 29, 1977).

II. Preemption Standards

The MDA contains an explicit preemption provision. *See* 21 U.S.C. § 360k. Section 360k states:

> **(a) General rule**
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[5]
>
> **(b) Exempt requirements**
>
> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applica-

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(Footnote continued from previous page)
warning requirements is not an issue which should have taken defendants by surprise.

[5] There is no question that Proposition 65 "relates" to the safety of dental mercury.

> ble to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement—
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

The State of California has not received an exemption from § 360k(a).

The Supreme Court has established the standard a district court applies when faced with a statutory preemption provision. *See Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). It said:

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," . . . "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation.

Id. at 2618. Therefore, the court looks only to the explicit preemption provision at § 360k(a), not to legislative history of congressional intent. The court also said:

> Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted. . . . Therefore, we need only identify the domain expressly pre-empted by [the pre-emption provisions].

Id. Pursuant to *Cipollone*, then, this court's task is to determine the preemptive reach of § 360k(a); that is, whether § 360k(a) extends to state reproductive toxicity warning re-

quirements for dental mercury or products containing dental mercury.

There is a general presumption against preemption, particularly in the regulation of health and safety matters, which are "primarily, and historically, a matter of local concern." *Chemical Specialties Manufacturers Ass'n, Inc. v. Allenby*, 958 F.2d 941, 943 (9th Cir. 1992), *cert. denied*, 113 S. Ct. 80 (1992). This presumption applies even when a statute contains an explicit preemption provision. *See Cipollone*, 112 S. Ct. at 2618 ("we must construe these provisions in light of the presumption against preemption"). Therefore, if the court were to find that the preemptive reach of § 360k(a) is not clear from a reading of the statute, the presumption against preemption would encourage this court to construe the preemption provision narrowly.

Here, the preemptive reach of § 360k(a) is clarified by FDA regulation.[6] *See* 21 C.F.R. § 808.1(d). Section 808.1(d) states:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) [360k(a)] of the act because they are not

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[6] The FDA's interpretation of § 360k(a) is controlling, so long as it is not contrary to congressional intent. *King v. Collagen Corp.*, 983 F.2d 1130, 1134-35 (1st Cir. 1993). Neither party has contested the validity of the regulations.

> "requirements applicable to a device" within the meaning of section 521(a) [360k(a)] of the act.

The regulation cites various examples of State or local requirements that are not regarded as preempted. The example relevant to this case is as follows:

> (1) Section 521(a) [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

See 21 C.F.R. § 808.1(d)(1).

III. Preemption

As discussed above, the MDA and its regulations do not impose a specific reproductive toxicity warning requirement on dental mercury. Therefore, it is clear that the FDA has not established "specific counterpart regulations" which would preempt state reproductive toxicity warning requirements. *See* 21 C.F.R. § 808.1(d). However, the language of the regulation makes clear that the MDA need not include a counterpart regulation in order to preempt state law. The issues remaining, then, are (1) whether "there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements," or (2) whether Proposition 65 is a "requirement of general applicability." *Id.*

A. Other Specific Requirements

The court finds there are "other specific requirements applicable to" dental mercury under the MDA and its regulations which render Proposition 65's warning requirement

"different from, or in addition to" the MDA's requirements. First, the FDA's refusal to impose a reproductive toxicity warning requirement on dental mercury is preemptive. Defendants[7] have argued that only an express provision of the MDA or its regulations can be preemptive. The court finds that the FDA's decision not to impose such a warning requirement must not be viewed as silence or as a failure to regulate. The MDA contains a specific provision granting the FDA the authority to impose such requirements, and the FDA affirmatively chose not to impose a reproductive toxicity warning requirement. *See* 21 U.S.C. § 360h. Given the FDA's authority to impose such a requirement, its decision was an exercise of that authority. Proposition 65 imposes a warning requirement which is different from the FDA's decision.

Second, the MDA also contains a specific requirement that medical devices, including dental mercury, bear adequate directions for use and adequate warnings. *See* 21 U.S.C. § 352(f). For prescription devices, the FDA has imposed specific requirements for an exemption from § 352(f), which includes a requirement that labelling bear information regarding "any relevant hazards, contra-indications, side effects, and precautions." Information regarding reproductive hazards would fall within this type of information. The parties do not dispute that dental mercury is a prescription device. The regulations state that prescription devices are "not safe except under supervision of a practitioner," such as a dentist. *See* 21 C.F.R. § 801.109. The regulation states that "adequate directions for use" *cannot* be prepared for such a device. As a result, devices such as dental mercury, must either comply with the specific warning provisions of 21

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[7] In this section, the court will use "defendants" to mean defendants and intervenor defendants.

C.F.R. § 801.109 or violate § 352(f). Proposition 65 imposes a warning requirement in addition to these requirements.

Defendants contend that these provisions are not "specific requirements" applicable to dental mercury, as they fall within the general controls applicable to all medical devices. Defendants point to several examples of warning requirements which apply only to one specific device. *See, e.g.*, 21 C.F.R. § 801.403; *see also* ELF's Motion, Exh. A. Defendants argue that § 808.1(d) contemplates this degree of specificity before it will preempt. Defendants read § 808.1(d) too narrowly. Section 808.1(d) does not state that the MDA preempts state law only when it contains a requirement specifically applicable to one specific device. A "specific requirement" may apply to numerous medical devices and still be preemptive. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.) (premarket approval procedure, applicable to all Class III devices, preempts state tort claims for defective design, inadequate warning and negligent failure to warn), *cert. denied*, 114 S. Ct. 86 (1993); *see also King v. Collagen Corp.*, 983 F.2d 1130, 1134-35 (1st Cir. 1993) (approval of device's labelling and packaging during Class III premarket approval process preempts state tort claims), *cert. denied*, 114 S. Ct. 84 (1993).

At the heart of this dispute is the fact that dental mercury, as a Class I device, is subject only to the requirements stated in the general controls and their attendant regulations. Neither party has cited a preemption case involving a Class I device, and the court has found none. Therefore, it appears that there is no authority directly on point. Defendants argue that if the general controls regulating a Class I device can be preemptive, "[t]he mere act of designating an item as a medical device would automatically deprive the states of all regulatory power over" that item. As a result, the argument goes, there would be no need for the word "specific" in § 360k(a) and § 808.1(d).

It is not dispositive that dental mercury is only a Class I device or that this court will be the first to find preemption in a case involving a Class I device. Since all medical devices are subject to the general controls, the court is just as persuaded by cases analyzing the preemptive effect of general controls on Class II or Class III devices. It appears to the court that the parties have cited only two published cases addressing the preemptive effect of general controls, and both cases found preemption. *See Mendes v. Medtronic*, 18 F.3d 13 (1st Cir. Mar. 9, 1994) (§ 801.109 preempts state tort claim based on manufacturer's failure to warn of pacemaker's latent defects); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Penn. 1992) (§ 360h preempts state tort claim based on manufacturer's failure to notify of defects), *aff'd*, 5 F.3d 1489 (3d Cir. 1993).

Therefore, for the reasons stated here and in *Mendes* and *Hunsaker*, the court hereby finds that Proposition 65's warning requirements, when imposed on dental mercury or products containing dental mercury, are different from, or in addition to, specific MDA requirements applicable to dental mercury or products containing dental mercury, and consequently are preempted.

B. Requirement of General Applicability

Alternatively, defendants argue that Proposition 65 is merely a state requirement of "general applicability" that "affects" devices but is not a "requirement applicable to a device" within the meaning of the MDA. *See* 21 C.F.R. § 808.1(d)(1). The court rejects the notion that Proposition 65 is akin to electrical codes or the Uniform Commercial Code. A state warning requirement relating to the safe use of chemicals is more akin to a state tort law relating to the safety of products and their use, *see Needham v. Int'l Playtex, Inc.*, 1989 U.S. Dist. LEXIS 800 (E.D. Ky. 1989), than it is to general codes which relate to the safety of public space or to the legal rights of consumers.

IV. Commerce Clause

Plaintiffs claim that Proposition 65 violates the Commerce Clause. To determine whether a state statute violates the Commerce Clause, a court must examine "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Brown-Forman Distillers v. New York*, 476 U.S. 573, 579 (1986). A court may properly strike down a state statute if its purpose is to disfavor interstate commerce, if its benefits are illusory or insignificant, or if the particular means chosen to achieve its goals are "irrational, arbitrary or unrelated to those goals." *Alaska Airlines, Inc. v. City of Long Beach*, 951 F.2d 977, 984 (9th Cir. 1991).

Plaintiffs' motion for summary judgment on this claim fails for two reasons. First, plaintiffs' have not submitted sufficient evidence for this court to rule, as a matter of law, that Proposition 65 places an unconstitutional burden on interstate commerce. Second, this issue is riddled with genuine issues of material fact. For instance, ELF argues that plaintiffs' claim that compliance with Proposition 65 is unduly burdensome lacks credibility in light of a recent voluntary settlement agreement in *Environmental Law Foundation v. Jeneric/Pentron*, San Francisco Superior Court No. 957039 (Dec. 13, 1993). However, John C. Miles, president of plaintiff Dentsply Int'l, Inc., and Gordon Cohen, president of Jeneric/Pentron, have submitted declarations stating that compliance with Proposition 65 is so burdensome that they may have to relocate their businesses to another state. *See* Miles Decl.; Moran Decl., Exh. 4. Cohen states that Jeneric/Pentron was forced to settle with ELF.

Based on *Brown-Forman*, *Alaska Airlines*, and the evidence submitted, the court cannot now say, as a matter of law, that Proposition 65 does or does not violate the Commerce Clause. Therefore, plaintiffs' motion for sum-

mary judgment on their Commerce Clause claim is DENIED, without prejudice.

V. Conclusion

For the foregoing reasons, the court hereby orders that:

1. Plaintiffs' motion for summary judgment on its declaratory and injunctive relief claims based on preemption is GRANTED;

2. Plaintiffs' motion for summary judgment on its declaratory relief claim based on a violation of the Commerce Clause is DENIED;

3. Defendants' motion to dismiss, or in the alternative, for summary judgment, is DENIED;

4. Intervenor defendant's motion to dismiss, or in the alternative, for summary judgment, is DENIED;

5. Defendants' motions to strike and for additional discovery are DENIED.

IT IS SO ORDERED.

DATED: AUG 23 1994

/s/

UNITED STATES DISTRICT JUDGE

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21 U.S.C. § 360k (1994)

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 808.1(d) (1995) (excerpt)

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

. . . .